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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/942,959 | 08/31/2001 | Robert S. Osbakken | 39187-1457 | 7962 |
| 20985 | 7590 | 06/20/2006 | EXAMINER | |
| FISH & RICHARDSON, PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | | JAGOE, DONNA A |
| ART UNIT | | PAPER NUMBER | | |
| | | 1614 | | |

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/942,959 | OSBAKKEN ET AL. | |
| | Examiner | Art Unit | |
| | Donna Jagoe | 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 March 2006.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 67-69,73-85,87,90-110,112 and 113 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 67-69,73-85,87,90-110,112 and 113 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/16/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

The amendment filed March 16, 2006 has been received and entered. Claims 67 has been amended.

Claims 67-69, 73-85, 87, 90-110, 112 and 113 are pending in this application.

Response to Arguments

Applicant's arguments filed March 16, 2006 have been fully considered but they are not persuasive. The rejection made in the paper mailed November 16, 2005 under 35 U.S.C. §103 over Rubin et al. U.S. Patent No. 5,925,334 (AE) in view of Schmitt et al. U.S. Patent No. 4,950,477 (AA) and Saunders Manual of Medical Practice (U) is maintained and hereby repeated for the reasons set forth in the previous office action and those set forth below.

Applicant asserts that the Examiner relies on Rubin et al. solely for the proposition that surfactants can lower the surface tension to enhance distribution and spreading of other medications to the lower respiratory tract. In response, Rubin et al. teach surfactant such as DPPC and Exosurf® mixed with an aerosolizing agent to promote mucus clearance (see abstract, see column 4, lines 5-15, see claim 1). The use of the surfactant lowers the surface tension to enhance distribution and spreading of other medications such as surfactant and an antibiotic and a surfactant and an inhaled anti-inflammatory agent for conditions *inter alia* such as **sinusitis** (column 10, lines 10-34). Methods of administration of the surfactant composition include a metered dose inhaler, dry powder inhalation, jet nebulization and ultrasonic nebulization (column 9, lines 28-39).

Regarding the amendment to specify the surface tension of the composition as about 10 to about 70 dynes/cm, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

In holding an invention obvious in view of a **combination of references**, there must be some suggestion, motivation or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention. This motivation may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. Here, filtered through the knowledge of one skilled in the art, Rubin et al. disclosed that clearance of mucus in the respiratory tract (including sinusitis (col. 10, lines 10-34)) can be achieved through inhalation of a surfactant combined with an aerosolizing agent and use of the surfactant lowers the surface tension to enhance distribution and spreading of other medications to the lower respiratory tract such as surfactant and an antibiotic and a surfactant and an

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inhaled anti-inflammatory agent for conditions such as sinusitis (column 10, lines 10-34). Schmitt et al. teach that the particle size is important because particles smaller than 0.5 μm are exhaled and thus not retained in the lungs while particles greater than 8.0 μm such as those produced in an atomizer do not reach the periphery of the lungs and therefore are not effective in preventing or treating the infection (column 2, lines 48-65). Saunders Manual is cited to teach the state of the art regarding treatment of sinusitis.

While applicant is correct regarding Schmitt being directed to treatment of lung conditions, the reference is cited to teach the particle size. If inhaled particles smaller than 0.5 μm are not retained in the lungs, it is reasonable to conclude that they would not remain in the sinuses since both the lung lining and the sinus lining would be termed "mucous membranes". Similarly, particles that are greater than 8.0 μm would be expected to not reach the periphery of the sinuses since Schmitt et al teach that such large particle sizes do not reach the periphery of the lungs.

Saunders Manual is cited to teach the state of the art regarding treatment of sinusitis. The agents cited in the instant claims are agents that are all well known in the art, in the treatment of sinusitis. Although the instant claims appear to be first to measure the surface tension in dynes, the HLB value, the NaCl equivalency, and the osmolality, that that discovery does not entitle him to remove the method of treating sinusitis from the public domain. It is noted that the surface tension of about 10 to about 70 dynes/cm includes the surface tension of ordinary water (72.8 dynes/cm).

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 90, 94, 95, 96, 97, 103, 104, 106, 108 and 109 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. The ranges claimed in the instant specification for surface tension contemplated for the invention is from 10-70 dynes/cm, greater than 70 dynes/cm, greater than 55 dynes/cm, greater than 50 dynes/cm, greater than 45 dynes/cm and ranges of from 10-40 dynes/cm, 20-40 dynes/cm and 30-40 dynes/cm, however, it is not found in the instant specification an instance where the surface tension is from 30-40 dynes/cm as recited in instant claim 90. This is a new matter rejection.

Regarding the osmolality, the ranges claimed in the instant specification for the osmolality contemplated for the invention is from 3-880 mOsm/kg, 150-880 mOsm/kg, 200-880 mOsm/kg, 300-700 mOsm/kg, 400-550 mOsm/kg and 300-880 mOsm/kg,

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however, an instance is not found in the specification wherein the osmolality is from about 400 mOsm/kg to about 700 mOsm/kg as in instant claim 94; or from about 500 mOsm/kg to about 600 mOsm/kg as in instant claim 95. This is a new matter rejection.

Regarding the hydrophile-lipophile balance (HLB) of between about 1.8 to about 8.6 in claim 96 and the HLB of between about 9.6 to about 16.7 in claim 97, when referring to the instant specification, page 24 recites a tutorial of surfactants that act as a solubilizing agent by forming micelles. An HLB value of 10 or higher means that the agent is primarily hydrophilic, while an HLB value of less than 10 means it would be lipophilic. For example, spans have HLB values ranging from 1.8 to 8.6, which is indicative of oil soluble for oil dispersible molecules. Tweens have HLB values that range from 9.6 to 16.7. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. There does not appear to be a description of how to make the claimed invention. Only a teaching of the HLB ranges of tweens and spans. This is a new matter rejection since it does not enable any person skilled in the art to which it pertains to make and use the claimed invention.

Regarding the NaCl equivalency, the ranges claimed in the instant specification for the osmolality contemplated for the invention are 0.2%-3%, 0.45%-1.8% and 0.9%-1.7%. However, an instance is not found in the specification wherein the NaCl

equivalency is from about 1.1% NaCl to about 1.8% NaCl as in claim 103; and about 1.3% NaCl to about 1.7% NaCl as in claim 104. This is a new matter rejection.

Regarding the particle size, the ranges claimed in the instant specification for the osmolality contemplated for the invention are from 1 to 5 μm , 0.5 to 10 μm , 2-4 μm , 1-4 μm and 0.5 to 10 μm . However, an instance is not found in the specification wherein the particle size range is about 3.0 to about 3.5 μm in diameter as in instant claim 106; or 0.5 to about 5.0 μm in diameter as in instant claim 108; or about 2.0 to about 3.5 μm in diameter as in instant claim 109. This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 99-102 and 106-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 99-102 and 106-110 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the instant specification refers to the particle size as mass median aerodynamic diameter (MMAD). This element is missing in the instant claims recited above. Amending the claims to recite the size range of about X to about X μm MMAD would obviate the rejection.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Donna Jagoe
Patent Examiner
Art Unit 1614

June 11, 2006



ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER